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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,115	LUO ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *4-15,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *February 27, 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to the Election filed November 12, 2003.

Claims 1 and 2 have been amended. New claims 16-20 are acknowledged. Claims 1-20 are pending in the instant application.

Claims 4-15 and 19-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on November 12, 2003.

Claims 1-3 and 16-18 have been examined to the extent they read on the elected subject matter.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-3), on November 12, 2003 is acknowledged. The traversal is on the ground(s) that the recombinant MINK3 nucleic acids of Group I and the recombinant MINK3 polypeptides of Group II should be examined together since the proteins are encoded by the nucleic acids. Applicants argue that examining the claims of Groups I and II together would not place an undue burden on the Examiner. Applicants rely on MPEP §808.02, where it states, "where the classification is the same and the field of search is the same, and there is no clear indication of separate future classification and field of search, no reasons exists for dividing among related inventions". Applicants contend that sequence databases are now organized such that search results for nucleic acid sequences routinely include any encoded amino acid sequences, and therefore a search of MINK3 nucleic acids and polypeptides would no place an undue examination burden on the Examiner.

Applicants arguments have been fully considered, but are not found persuasive because, as argued in the previous Restriction Requirement, Inventions of Groups I and II are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case, Group I is separate and distinct from Group II because the inventions are directed to different chemical types regarding the critical limitations therein. For example, for Group I, the critical feature is a nucleic acid, whereas for Group II, the critical feature is a polypeptide. It is acknowledged that various processing steps may cause the nucleic acid of Group I to be directed to the polypeptide of Group II, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. The separate chemical types of the invention of Groups I and II are further supported by their different classification and separate status in the art. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if searched together, as compared to being searched separately. For these reasons, each of Groups I and II is separate and distinct from each other.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The Information Disclosure Statement, filed February 27, 2003 is acknowledged. The references referred to therein have been considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 1 is drawn to a recombinant nucleic acid, or its complement, capable of hybridizing, in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5, which encodes a MINK3 protein. Claim 2 is drawn to a recombinant nucleic acid, or its complement, comprising a nucleic acid sequence having at least about 90% identity to SEQ ID NO:1, 3, and 5, which encodes a MINK3 protein. Claim 3 is dependent of claim 1 or 2, and includes all the limitations of claim 1 or 2, with the further limitation, wherein said nucleic acid comprises a nucleic acid sequence selected from SEQ ID NOs:1, 3, and 5, or complements thereof.

The first issue is would a recombinant nucleic acid, or its *complement*, capable of hybridizing, in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5, encode a MINK3 protein as claimed? The second issue is would the *complement* of a recombinant nucleic acid comprising SEQ ID NOs:1, 3, and 5, encode a MINK3 protein as claimed? The third issue is would a recombinant nucleic

acid sequence, or its *complement*, having *at least about 90% identity* to SEQ ID NOs:1, 3, and 5, encode a MINK3 protein as claimed? The instant Specification teaches SEQ ID NOs:1, 3, and 5 encode a MINK3 protein. Applicants have not described a recombinant nucleic acid, or its complement, capable of hybridizing, in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5, which encode a MINK3 protein. Further, Applicants have not described a complement of a recombinant nucleic acid comprising SEQ ID NOs:1, 3, and 5, or a recombinant nucleic acid sequence, or its complement, having at least about 90% identity to SEQ ID NOs:1, 3, and 5, which encodes a MINK3 protein.

Applicant is referred to the Guidelines on Written Description, published at FR 66(4) 1099-1111 (January 5, 2001) (also available at www.uspto.gov). The following passage is particularly relevant:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species, by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within a genus, one must describe a sufficient number of species to reflect the variation within the genus. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. In an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.

The central issue of this rejection is whether Applicant has described a sufficient number of species to adequately represent the genus of a recombinant nucleic acid, or its complement, capable of hybridizing, in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of

60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5, which encodes a MINK3 protein; the complement of a recombinant nucleic acids comprising SEQ ID NOs:1, 3, and 5, which encodes a MINK3 protein; or a recombinant nucleic acid sequence, or its complement, having at least about 90% identity to SEQ ID NOs:1, 3, and 5, which encodes a MINK3 protein.

The claims are so broad to include *any* recombinant nucleic acid, or its complement, capable of hybridizing, in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5; the complement of a recombinant nucleic acids comprising SEQ ID NOs:1, 3, and 5; or a recombinant nucleic acid sequence, or its complement, having at least about 90% identity to SEQ ID NOs:1, 3, and 5; all of which encodes a MINK3 protein. Thus, the claimed genus is likely to be very large, and to have substantial variability. The specification only teaches SEQ ID NOs:1, 3, and 5 encode a MINK3 protein, but has not described a *any* recombinant nucleic acid, or it complement, capable of hybridizing, in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5; the complement of a recombinant nucleic acids comprising SEQ ID NOs:1, 3, and 5; or a recombinant nucleic acid sequence, or its complement, having at least about 90% identity to SEQ ID NOs:1, 3, and 5, all of which encodes a MINK3 protein. In fact, regarding a recombinant nucleic acid sequence having at least about 90% identity to SEQ ID NOs:1, 3, and 5, which encodes a MINK3 protein, the art teaches a nucleic acid that is almost 92% identical to SEQ ID NO:1, encodes a MINK1 protein (see Ippeita et al., 2000 FEBS Letters, Vol. 469:19-23).

The specification does not adequately describe the structure and physical properties of a recombinant nucleic acid, or it complement, capable of hybridizing, in a solution containing

1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5; the complement of a recombinant nucleic acids comprising SEQ ID NOs:1, 3, and 5; or a recombinant nucleic acid sequence, or its complement, having at least about 90% identity to SEQ ID NOs:1, 3, and 5, all of which encodes a MINK3 protein. Further, it is unclear how the *complement* of a recombinant nucleic acid, capable of hybridizing in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5; the *complement* of a recombinant nucleic acid of SEQ ID NO:1, 3, and 5; or the *complement* of a recombinant nucleic acid having at least about 90% identify to SEQ ID NO:1, 3, and 5, will encode a MINK3 protein. It is recognized in the prior art that the function of a protein depends on the sequence of its amino acids in a certain pattern, conformation of the protein due to the amino acid sequence, and the functional properties of the different parts of the protein (see second paragraph in Rudinger J in Peptide Hormones. Editor Parsons JA. Pages 1-7, 1976, University Park Press, Baltimore). Rudinger further add, "The significance of particular amino acids and sequences for different aspects of biological activity can not be predicted *a priori* but must be determined from case to case by painstaking experimental study" (see conclusion on page 6).

In summary, the Specification teaches SEQ ID NOs:1, 3, and 5 encode a MINK3 protein, but has not described a recombinant nucleic acid, or its complement, capable of hybridizing, in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5; the complement of a recombinant nucleic acids comprising SEQ ID NOs:1, 3, and 5; or a recombinant nucleic acid sequence, or its complement, having at least about 90% identity to SEQ ID NOs:1, 3, and 5, all of which encodes a MINK3 protein, as

instantly claimed. One of skill in the art would expect the claimed genus of recombinant nucleic acids to comprise substantial variability, and the art of deducing structure/function relationships in proteins is highly unpredictable. In view of the variability of the claimed genus, the number of disclosed species, and the failure to provide the structure and physical properties of a recombinant nucleic acid, or its complement, capable of hybridizing, in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5; the complement of a recombinant nucleic acids comprising SEQ ID NOs:1, 3, and 5; or a recombinant nucleic acid sequence, or its complement, having at least about 90% identity to SEQ ID NOs:1, 3, and 5, all of which encodes a MINK3 protein, which would allow one to accurately predict the recombinant nucleic acids which possess such activity, one of skill in the art would conclude that Applicant was not in possession of the claimed invention at the time of filing. Further, it is unclear how the complement of a recombinant nucleic acid, capable of hybridizing in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5; the complement of a recombinant nucleic acid of SEQ ID NO:1, 3, and 5; or the complement of a recombinant nucleic acid having at least about 90% identify to SEQ ID NO:1, 3, and 5, will encode a MINK3 protein, where Applicants have not disclosed a representative number of species.

Claim Rejections - 35 USC § 102

Claims 1-3 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ippeita et al. (FEBS Letters, 2000 Vol. 469:19-23).

Claim 1 is drawn to a recombinant nucleic acid, or its complement, capable of hybridizing, in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid comprising SEQ ID NOs:1, 3, and 5, which encodes a MINK3 protein. Claim 2 is drawn to a recombinant nucleic acid, or its complement, comprising a nucleic acid sequence having at least about 90% identity to SEQ ID NO:1, 3, and 5, which encodes a MINK3 protein. Claim 3 is dependent of claim 1 or 2, and includes all the limitations of claim 1 or 2, with the further limitation, wherein said nucleic acid comprises a nucleic acid sequence selected from SEQ ID NOs:1, 3, and 5, or complements thereof. Claim 16 is drawn to a recombinant nucleic acid, comprising a nucleic acid that encodes MINK3 protein comprising an amino acid sequence selected from SEQ ID NOs:2, 4, and 6. Claims 17 and 18 are dependent on claims 1, 2, or 16, and include all the limitations of claim 1, 2, or 16, with the further limitations of a host cell and expression vector comprising said nucleic acids.

Ippeita et al. disclose the molecular cloning of MINK1 (see Figure 2). MINK1 is almost 92% identical to SEQ ID NO:1 (MINK3) of the instant invention (see attached sequence alignment), and thus meets the limitations of claims 2 and 3. The MINK1 disclosure of Ippeita et al. further meets the limitations of claim 16 because claim 16 recites "a nucleic acid sequence that encodes a MINK3 protein *comprising* an amino acid sequence of SEQ ID NOs: 2, 4, and 6". The term "comprising" is open language and therefore the nucleic acid sequence of MINK1 disclosed by Ippeita et al. encompasses the nucleic acid sequence that encodes a MINK3 protein, comprising an amino acid sequence of SEQ ID NO:2, as recited in claim 16. Ippeita et al. disclose full length MINK1 was cloned into a pCMV expression vector and transiently expression in HEK 293 cells (see Figure 5), and thus meets the limitations of claims 17 and 18.

Ippeita et al. further disclose total RNAs were hybridized with a MINK cDNA probe labeled by [α-^{32}P]dCTP (see Figure 1). Ippeita et al. disclose the hybridization conditions were performed in 4x SSC, 1mM EDTA, 0.1% Ficoll type 400, 0.1%polyvinylpyrrolidone, 1% SDS, and 200 μg/ml denatured salmon sperm DNA at 65°C (see page 19, [2.2].). It is noted that the hybridization conditions disclosed by Ippeita encompass a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C as recited in claim 1. Since MINK1 and MINK3 (SEQ ID NO:1 of the instant invention) share a high degree homology (92%), it is expected that the MINK1 probe disclosed by Ippeita et al. would be capable of hybridizing capable of hybridizing, in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid of SEQ ID NO:1 of the instant invention (MINK3), and thus meets the limitations of claim 1.

Therefore, Ippeita et al. anticipate the instant invention.

Claims 1-3 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Plowman et al. [U.S. Patent No. 6,656,716] ('716 Patent).

Claims 1-3 and 16-18 are drawn to the inventions as described above in the rejection under 35 U.S.C. 102(b) as being anticipated by Ippeita et al.

The '716 Patent discloses human ZC3 (see SEQ ID NO:11 and Figure 9J) which is 92% identical to SEQ ID NO:1 of the instant invention (see attached sequence alignment) and thus meets the limitations of claims 2 and 3. The human ZC3 disclosure of the '716 Patent further meets the limitations of claim 16 because claim 16 recites "a nucleic acid sequence that encodes a MINK3 protein *comprising* an amino acid sequence of SEQ ID NOs: 2, 4, and 6". The term "comprising" is open language and therefore the nucleic acid sequence of ZC3 disclosed by the

'716 Patent encompasses the nucleic acid sequence that encodes a MINK3 protein, comprising an amino acid sequence of SEQ ID NO:2, as recited in claim 16. The '716 Patent also discloses the invention features isolated, enriched, or purified nucleic acid molecules encoding kinase polypeptides, further comprising a vector or promoter effective to initiate transcription in a host cell, and thus meets the limitations of claim 17. The invention features recombinant nucleic acids containing SEQ ID NO:11 in a cell or an organism (see column 10, lines 4-22), and thus meets the limitations of claim 18. The 716' Patent further discloses an aspect of the invention features a nucleic acid probe for the detection of a nucleic acid encoding a kinase polypeptide in a sample (see column 12, lines 39-41). The nucleic acid probe contains a nucleotide base sequence that will hybridize to a sequence of SEQ ID NO:11 (see column 12, lines 55-63). The hybridization conditions include various low or high stringency hybridization conditions, which are well known to those skilled in the art, including hybridization in 50% formamide, 5xSSC, 50 mM NaH_2PO_4, pH 6.8, 0.5% SDS, 0.1 mg/ml sonicated salmon sperm DNA, and 5xDenhaart solution at 42°C overnight (see column 9, lines 53-57). Since human ZC3 and MINK3 (SEQ ID NO:1 of the instant invention) share a high degree homology (92%), it is expected that the ZC3 probe disclosed by the '716 Patent would be capable of hybridizing, in a solution containing 1.0M Na+ ion, pH 7.0-8.3, at a temperature of 60°C, to a nucleic acid of SEQ ID NO:1 of the instant invention (MINK3), and thus meets the limitations of claim 1.

Therefore, the '716 Patent anticipates the instant invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term "capable of" which denotes a latent property, making it unclear it the property following the recitation "capable of" is intended to actually forma a part of the claimed invention.

Claim Objections

Claim 2 is objected to because of the following informalities: Claim 2 contains two periods at the end of the claim. Appropriate correction is required.

Conclusion

No claims are allowable. However, the Examiner would like to point out that a recombinant nucleic acid consisting of SEQ ID NOs:1, 3, or 5, wherein said recombinant nucleic acid encodes a MINK3 protein, is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (571) 272-0758. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg
March 3, 2004